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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,610

06/16/2005

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27656/40760

3634

4743

7590

11/25/2009

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

11/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/518,610	<b>Applicant(s)</b> GHANEM ET AL.	
	<b>Examiner</b> ANISH GUPTA	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6,11,16,18,20,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,16,18 and 20 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 23-24 submitted, 2-03-09, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly added claims are drawn to method of treating cancer and method of treating other disorders selected from AIDs, parasitic disease etc. . . These claims corresponded to Group III in the restriction requirement mailed 10-4-07. In response to the restriction requirement, Applicants canceled all of the claims drawn to Groups II-VI. Examination was conducted on the claims corresponding to Group I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. All rejections made in the previous office action and not cited herein are hereby withdrawn. The rejection of Lewensohn has been amended to include claims 1-2, 6, 16, 18, 20 based on applicant's disclosure and is a new grounds for rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

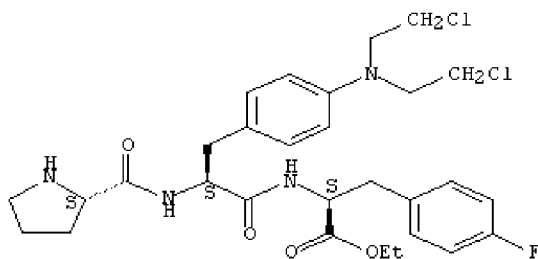
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1-2, 6, 16, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewensohn et al. (WO01/96367).

The claims are drawn to a tripeptide or tripeptide esters selected, where the tripeptide includes Pro-Phe-Phe and has a substituent at the not terminal amino acid moiety, with the proviso that said substituent is not  $-\text{N}(\text{CH}_2\text{-CH}_2\text{-Cl})_2$  in the meta position on the not terminal Pro-Phe-p-F-Phe.

The reference disclose the compound:



This compound is L-prolin-L-melphanyl-p-Fluorophenylalaline ethyl ester and is useful in treating malignant tumors (see claims). Note that the peptide sequence is Pro-phe-F-Phe, which meets the limitation of claims 21-22. The reference contains the substituent  $\text{N}(\text{CH}_2\text{-CH}_2\text{-Cl})_2$  in the central Phe residue. This compound meets the limitation of the claims because the instant specification states that page 3 that pharmacologically active groups include  $-\text{N}(\text{CH}_2\text{-CH}_2\text{-Cl})_2$  (see page 3, lines 15-17). Furthermore, example 1 disclose a similar compound, except the  $-\text{N}(\text{CH}_2\text{-CH}_2\text{-Cl})_2$  is in the para position, and states that "[t]his particular substituted tripeptide is bearing an alkylating group at the sarcolysine moiety. Said alkylating group is assumed to be the pharmacologically active part of the such substituted phenylalanine (*sic.*) moiety or - in other words- the drug loaded on the phenylalanine moiety." (see page 9, lines 16-24). Based this teaching, one

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can conclude that the even though -N(CH<sub>2</sub>-CH<sub>2</sub>-Cl)<sub>2</sub> is part of the sarcolysyl moiety, the drug is still loaded on the phenylalanine moiety. Thus, this meets the limitation of the claims.

Thus, the reference anticipates the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation the alkyl group is a methyl or ethyl group, and the claim also recites preferably an ethyl group which is the narrower statement of the range/limitation. The MPEP states use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible. Description of examples and preferences is properly set forth in the specification rather than in a single claim. A narrower range or preferred embodiment may also be set forth in another independent claim or in a

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dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. See MPEP 2173.05(c). Here it is unclear if the claim scope is inclusive of both the methyl and ethyl or just the preference recited of ethyl.

5. Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/  
Primary Examiner, Art Unit 1654